UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,312	02/12/2004	Wolfgang Geiger	32860-000688/US	4081

30596 7590 01/26/2005

HARNESS, DICKEY & PIERCE, P.L.C.
P.O.BOX 8910
RESTON, VA 20195

EXAMINER	
TOOR, SADAF A	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,312	GEIGER, WOLFGANG	
	Examiner	Art Unit	
	Sadaf Toor	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-17 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-17 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/4/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed November 4, 2004. The Examiner acknowledges the amendments to the drawings, the amendments to the abstract, the cancellation of claims 3 and 18, and the amendments to claims 1 and 16. Claims 1-2, 4-17, and 19-21 are pending.

Drawings

2. The proposed drawing correction received November 4, 2004 is approved by the Examiner.

Claim Objections

3. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 depends from claim 2 and recites the limitation "the data evaluation device is integrated into the holding device." Claim 2 depends from claim 1, which recites the same limitation on line 5. Claim 7 fails to further limit claim 2.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-2, 6-7, 14-17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaylor et al. ('219) in view of Kreiser et al. ('843) for the reasons set forth in the previous office action.

Regarding claims 1, 7, and 16, Kaylor et al. teach a healthcare network (best illustrated in Fig. 2) including a biosensor (20) which can include microneedle devices (see paragraph [0262]), a holding device for supporting the microneedle array (an article of clothing as described in paragraphs [0036], [0277], and [0310]), a data recording device connected to the microneedle array for recording data obtained from the microneedle array (biosensor (20) itself records the data and arrives at analyte measurement (60)), a data evaluation device connected to the data recording device for evaluating the recorded data (data allocation and processing (26)), and a display device connected to the data evaluation device for displaying data (measurement display and interpretation (62)). Kaylor et al. further disclose that the holding device can be an article of clothing such as gloves (see paragraphs [0036], [0277], and [0310]). However, Kaylor et al. fail to teach that the display device is arranged on the holding device.

Kreiser et al. teach a hand-mounted device for obtaining a sample of blood from the scalp of a fetus and for measuring the pH of the blood sample. Fig. 1 shows the device (100) mounted on a surgical glove (102) as described in paragraph [0016]. A data evaluation device (pH electrode (128)) analyzes the blood and the result is displayed on the display means (electronic pH meter (132)). The display means (electronic pH meter (132)) is apparently part of the device (100); therefore, it is fully capable of being mounted on surgical glove (102) as well. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to combine the teachings of the Kaylor et al. biosensor system with the teachings of the hand-

mounted pH measuring device of Kreiser et al., for the purpose of obtaining a diagnostic article with a display device arranged on the holding device or glove such that all components are disposed conveniently on the user's hand.

Applicant's amendment to claims 1 and 16 to recite "a data evaluation device *integrated* into the holding device" does not render the claims patentable over the prior art. Applicant is directed to *In re Larson*, 144 USPQ 347 (CCPA 1965), which states that making parts integral is merely a matter of obvious engineering design choice. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide a diagnostic article similar to that of Kaylor et al. and Kreiser et al. with the data evaluation device integrated into the holding device since it has been held that making parts integral is obvious (see the case law cited above).

Referring to claims 2 and 17, Kaylor et al. further teach that a dosing unit (a drug delivery device as described in paragraphs [0258] and [0262]) can be fully attached or integrated with the biosensor. In particular, Kaylor et al. state that one or more microneedles first measure a biological condition in the blood or tissues of the body, then based on what is detected by a probe or other sensor (a data evaluation device) associated with one or more of the microneedles, other microneedles may deliver a therapeutic treatment. Since the dosing unit is attached or integrated with the biosensor, and the data evaluation device is associated with the microneedles of the biosensor, then the dosing unit itself is connected to the data evaluation device.

With regard to claims 6, 14-15, and 21, the Kaylor et al. healthcare network relates to particular combinations of sensor technologies (biosensors which can include microneedle devices) and information management systems and/or health management systems for the benefit

of the user, including embodiments wherein a degree of personal control over data sharing is maintained for user privacy. In essence, the purpose of this network is to provide a link between the data evaluating means of the diagnostic article and an electronic patient record, which would be contained in a management system.

6. Claims 4-5, 8-13, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaylor et al. ('219) in view of Kreiser et al. ('843) as discussed above, and further in view of Olson ('113) for the reasons set forth in the previous office action.

With regard to claims 4, 8-10, and 19, which claim the maximum height of a microneedle to be 2mm, Olson teaches microneedles and methods of manufacture and use thereof. In paragraph [0048] Olson states that microneedles used for minimally invasive penetration through a biological barrier usually have a height ranging from 200 to 2000 μm, which is equivalent to 0.2 to 2 mm.

With regard to claims 5, 11-13, and 20, which claim the maximum diameter of a microneedle lumen to be 150 μm, Olson further states (in paragraph [0048]) that microneedles used for minimally invasive penetration through a biological barrier typically have a lumen diameter ranging from 70 to 150 μm.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form a diagnostic article similar to that of Kaylor et al. with the modifications of Kreiser et al. as discussed above, with the microneedles of Kaylor et al. having the dimensions suggested by Olson as an obvious engineering design choice.

Response to Argument

7. Applicant's arguments filed November 4, 2004 regarding the rejection of claims 1-3, 6-7, 14-18 and 21 under 35 U.S.C 103(a) have been fully considered but they are not persuasive.

8. Applicant's argument, see page 8, that pH meter (132) is external to glove (102) is not persuasive. Examiner holds to the original position that Kreiser et al. do not teach pH meter (132) being remote from glove (102). Although the pH meter is not illustrated as being arranged on the glove in Fig. 1, the specification does not teach that pH meter (132) is a separate device from device 100. Since device 100 is mounted on glove (102) (see paragraph [0016], lines 3-4) and pH meter (132) is apparently part of device 100, then the pH meter is also mounted on the glove (102). Examiner burdens Applicant to show that the specification teaches that the pH meter (132) is remote from the glove (102).

9. In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Kaylor et al. and Kreiser et al. teach hand-mounted sampling devices. As stated in the previous office action and above, Kaylor et al. teach microneedles associated with a glove and a display device for outputting a reading to the user (see paragraphs [0071], [0262], and [0277]). Kreiser et al. teach a sampling needle mounted on a glove (102) and a

display device (132) associated with the glove. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to combine the teachings of Kaylor et al. and Kreiser et al. to provide a diagnostic article with all components disposed on the operator's hand for convenience of use.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sadaf Toor whose telephone number is (571) 272-4734. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sat
1/24/05

CHARLES MARMOR
PRIMARY EXAMINER